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EXAMINER	
WOLF, MEGAN YARNALL	

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/828,841	KLADAKIS ET AL.	
	Examiner	Art Unit	
	MEGAN WOLF	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-23,25 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-23,25 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/24/08 have been fully considered but they are not persuasive.

2. Regarding claim 1, Applicant argues that Malaviya '797 does not disclose that the conduit flap extends to the synovium. However, claim 1 is an apparatus claim and this limitation is directed to the intended use of the device. The cell growth conduit flap of Malaviya is entirely capable of being positioned such that the flap extends to the synovium as the claim requires.

3. Applicant's arguments with respect to claims 21 and 25 have been considered but are moot in view of the new ground(s) of rejection.

4. Arguments regarding the rejection of claims 1 and 18 as being anticipated by Malaviya '344 are not persuasive for the same reasons as discussed above regarding the rejection of claim 1 in view of Malaviya '797. Applicant further argues that Malaviya '344 does not disclose that the cover/flap is adapted to communicate biological materials to the tissue defect in the meniscus, however, the cover materials disclosed by Malaviya '344 and '797, including ECM, bioremodelable material, and biocompatible polymers, are all capable of communicating biological materials to the tissue defect in the meniscus.

5. Applicant's arguments regarding the rejection of claims 9, 24, and 26 under 35 U.S.C. 103(a) as being unpatentable over Malaviya '797 are not persuasive. Applicant argues that the tabs disclosed by Malaviya are for the purpose of fastening the device to

the surrounding tissue and that Malaviya does not disclose that tabs allow cells and nutrients to travel to the defect in the meniscus and encourage healing of the meniscus. The Examiner disagrees as the tabs are simply an extension of the cover which is disclosed to be a material that allows cells and nutrients to travel to the defect. Figure 41 illustrates use of the tabs described in par. 38. Clearly the tabs, which are an extension of the cover, contact the synovium. The claim only requires that the flap allows cell and nutrients to the defect and therefore only requires that the cover does not inhibit cells and nutrients from traveling to the defect. Further the claim does not require that blood or synovial fluid is allowed to travel to the inner portion of the device as argued by Applicant on page 9 lines 12-14.

6. Regarding arguments about the rejection of claims 22, 23, 28, and 29, see the above discussion of the rejection of claims 9, 24, and 26.

7. Arguments regarding claim 19 are not persuasive as it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 2, 4-8, 10-17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Malaviya et al. 2003/0036797.

10. Re claim 1, Malaviya discloses a biocompatible meniscal repair device, comprising a biocompatible tissue repair scaffold 250 (figs. 26-29) and cell growth conduit flap 232,234 attached to the tissue repair scaffold (fig 29), the cell growth conduit flap being adapted to communicate biological materials to a tissue defect in the meniscus (flaps have open space to communicate biological materials from the vascularized area in which it contacts, par.24). Regarding the intended use of the device as claimed, the repair scaffold is capable of being placed in contact with a defect in a meniscus and the cell growth conduit flap is capable of contacting a tibial surface and extending to the synovium.

11. Re claim 2, see par.153.

12. Re claim 4, Malaviya discloses that the scaffold is made of SIS (small intestine sub mucosa) or other ECM material (par.157), which is known in the art to be bioresorbable.

13. Re claim 5, Malaviya discloses that the compartments which form the scaffold could be made of a biocompatible polymer in substitute of ECM material, or can be made of a composite of the two (par.182, noting that it says it can be applied to other embodiments of the invention, such as fig. 29). The cell growth conduit flap can be

made from an ECM material (par.138). Therefore, the scaffold and the flap can be made from different materials.

14. Re claim 6, Malaviya discloses that both the scaffold and the flap can be made of the same materials (pars.138, 157).

15. Re claims 7 and 8, Malaviya discloses that the scaffold and cell growth conduit flap include a least one polymer derived from monomers selected from the group consisting of glycolide, lactide, and dioxanone (par.11 states that a mass is filled within the flap space, such as the scaffold and the flap would include within them said mass. Par.11 also states in various embodiments the mass can be made of biocompatible polymers, which is later disclosed as glycolide, lactide, dioxanone, and other polymers in par.36. Furthermore, the flap and scaffold could be made in part of these materials as described in par.182).

16. Re claim 10, Malaviya discloses that the scaffold is made from naturally occurring ECM as explained above with respect to claim 6 and therefore inherently contains natural polymers.

17. Re claim 11, Malaviya discloses that viable tissue is disposed within the scaffold (biologically derived agents, par.159 - the agents can be tissue as described in par.33). It is inherent that the tissue would integrate with the native tissue.

18. Re claims 12 and 13, Malaviya discloses that the scaffold can contain within it bioactive agents (par.159) including growth factors or other agents that stimulate cell growth (par.32).

19. Re claim 14, the cell growth conduit flap and scaffold can be formed from a single piece, as they both can be made from the same large sheet of ECM material and cut as desired to form the specific parts.

20. Re claims 15-17, Malaviya discloses in Figure 29 that the flap and scaffold are oriented together that they are substantially perpendicular. Furthermore, the scaffold conical sections are capable of being oriented in other directions to form shapes of a "T" or "L".

21. Re claim 20, see fig. 29.

22. Claims 1 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Malaviya et al. 2004/0143344. Malaviya discloses a biocompatible meniscal repair device comprising biocompatible tissue repair scaffold 14 (fig. 9), and a cell growth conduit flap attached to the tissue repair scaffold (Fig. 9, part 12, layered cover) capable of communicating biological materials to a tissue defect in the meniscus (par.49). Regarding the intended use of the device, the scaffold is capable of being placed in contact with a defect in a meniscus (Fig. 8 and 8a), and the cell growth conduit flap is capable of being placed such that it contacts a tibial surface and extends to the synovium.

23. Re claim 18, Malaviya discloses that the thickness of the cell growth conduit flap is less than the thickness of the tissue repair scaffold, as clearly shown in Fig. 9.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2004/0143344 in view of Malaviya et al. 2003/0044444. Malaviya '344 discloses the invention substantially as claimed including that the cell growth conduit flap can be made from ECM material (par.49). However, Malaviya '344 does not disclose that the density is in the range of about 150-350 mg/cc. Malaviya '444 discloses an ECM scaffold that can be made to have a desired density (par.35). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ECM material disclosed by Malaviya '344 in view of the teaching of Malaviya '444, as it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

26. Claims 9, 21, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2003/0036797.

27. Re claim 9, Malaviya discloses that the scaffold and flap can include glycolide and L-lactide as explained above with respect to claims 7 and 8. Malaviya also discloses that any copolymer used in implants can be utilized (par.36). Malaviya does not specifically state that this device uses the copolymer of glycolide and L-lactide, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the material with the copolymer of glycolide and L-

lactide, as it is well known in the art to use the copolymer of glycolide and L-lactide and Malaviya states that copolymers can be used.

28. Re claims 21 and 25, Malaviya discloses a method of surgically repairing meniscal defects, comprising: providing a tissue repair scaffold having attached thereto a cell growth conduit flap (see explanation above for claim 1), positioning the tissue repair scaffold in contact with a defect in a meniscus while positioning the cell growth conduit flap in contact with a tibial surface (par.24; the scaffold is in a defect area, and therefore is in contact with the defect), and fixing the tissue repair scaffold in position (par.156 explains that the scaffold is placed in position in between the conduit flaps), wherein the cell growth conduit flap allows cells and nutrients to travel to the defect in the meniscus and thereby encourage healing of the meniscus (par.24, explains that blood and fluid would travel to the inner portion of the device to regenerate the meniscus). Malaviya does not explicitly disclose that the cell growth conduit flap is in contact with the synovium. However, Malaviya does state that one or more of the layers of the material forming the upper cover or the lower cover may be formed to provide tabs extending away from the device to facilitate attachment to the surrounding tissue (par.38). This would still be attached and apart of the growth conduit flap, and could extend to the synovium (see fig.41 for example), as it is a surrounding tissue of the meniscus. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the cell growth conduit flap in contact with the synovium, as it would allow for attachment of the device as explained above.

29. Re claim 27, the cover materials disclosed by Malaviya are capable of acting as a conduit that enables cells and nutrients to travel from the synovium to the tissue defect in the meniscus.

30. Claims 22-23 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2003/0036797 in view of Li et al. 4,790,819. Malaviya discloses the invention substantially as claimed and as discussed above but does not disclose the step of rasping the meniscus before positioning the cell growth conduit flap. However, Li discloses in the background of the invention, first paragraph, that the initial phase in wound repair is a fibrin clot. They further state that this is absent in meniscal tears, and the synovium and meniscus are rasped to get the blood supply into the area to be able to form a clot (therefore the step would be before positioning any devices in the tear, as it should be the initial phase of the healing). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the step of rasping the meniscus and synovium before placing the cell growth conduit flap in position in view of the teaching of Li, as it can provide an increased blood supply to help promote wound repair, as explained in the first paragraph of the background of the invention.

Conclusion

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEGAN WOLF whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 7:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738
8/5/08

/Bruce E Snow/

Primary Examiner, Art Unit 3738